UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,043	05/21/2002	Jean A. Chmielewski	7040-363	6179

7590 05/05/2004

Thomas Q Henry
Woodard Emhardt Naughton Moriarty & MCNett
Bank One Center Tower
111 Monument Circle Suite 3700
Indianapolis, IN 46204-5137

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,043	CHMIELEWSKI ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6 and 11-14 in the response filed 7 January 2004 is acknowledged. The traversal is on the ground that a search of all claims would not impose a serious burden. This is not found persuasive because the instant application is a 371, wherein the sole criterion for a restriction is unity of invention.

With regard to the requirement for an election of species, Applicant's election with traverse of lactose is acknowledged. Applicant appears to argue that the Markush group recited in claim 14 is sufficiently few in number or so closely related that the search and examination of the entire claim can be made without serious burden. The examiner does not agree that a Markush group comprising thirty individual members *and any derivatives, salt forms, or mixtures thereof* is not one that contains a "few" members. Neither does the examiner agree that a Markush group that comprises such members as sucrose, glycine, sodium saccharine, and zinc is one that comprises "closely related" members.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by CHEN et al (EP 052413).

The claims recite inclusion of an active pharmaceutical ingredient (API) is included in the crystal wherein the API is included in the crystal "in a growth-sector specific orientation." From a review of the specification, this limitation is interpreted as an inherent characteristic derived from the process wherein the API is included preferentially at a certain face of any given crystal-lattice component.

CHEN discloses the co-crystallization of an API with sucrose. See examples 7-9 and 13 and page 8. The reference is silent with regard to the API being included in the crystal in a growth-sector specific orientation. However, the product is prepared from a saturated solution in a manner similar to the instant product, and the reference teaches that "the active ingredient is incorporated as an integral part of the sugar matrix." Therefore, it appears that the reference product inherently comprises the required limitations. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN et al (EP 052413).

The invention is drawn to a pharmaceutical composition comprising a crystal-lattice component wherein an API (different from the crystal-lattice component) is included within a growth-sector of said crystal-lattice component. Dependents recite the use of at least two crystal-lattice components, the addition of adjuvant(s), the wt% of the API in the composition, and the limitation that the API be a "biopharmaceutical." As defined by Applicant, a biopharmaceutical is one that is polymeric in nature

CHEN teaches as set forth above.

The reference does not exemplify a second crystal lattice component or an adjuvant. However, CHEN does specifically suggest the addition of other lattice components, such as monosaccharides and other disaccharides with the saturated sucrose syrup. See page 5, 1st full paragraph.

The reference does not teach wt% range recited in claim 6. However, example 7 teaches a composition wherein the API is just over 1 wt%.

The reference does not exemplify inclusion of a biopharmaceutical. Example 10 exemplifies the inclusion of invertase. This enzyme does not have utility as a biopharmaceutical, but the example demonstrates the suitability for the inclusion of useful enzymes, as suggested in the reference at the paragraph bridging pages 4 and 5.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the sucrose-API compositions as taught by CHEN for the art-disclosed utility. It would be obvious to add another crystal lattice component, as suggested by the reference. This second component would also be considered an adjuvant. It would be within the scope of the artisan to select any appropriate API, including polymeric ones, as the reference suggests their use and demonstrates the suitability for their inclusion. As discussed above, the reference exemplifies a composition having just over 1 wt%. It would be within the scope of the artisan to optimize the wt% for the desired dosage of the particular API.

o

Allowable Subject Matter

The claims, limited to the use of the elected species, lactose, appear to be free of the art.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
April 30, 2004